

Submitted via PMPRB's Consultation Portal

Patented Medicine Prices Review Board Standard Life Centre  
Box L40 333 Laurier Avenue West  
Suite 1400 Ottawa, ON K1P 1C1

**RE: 2022 Proposed updates to the PMPRB Guidelines**

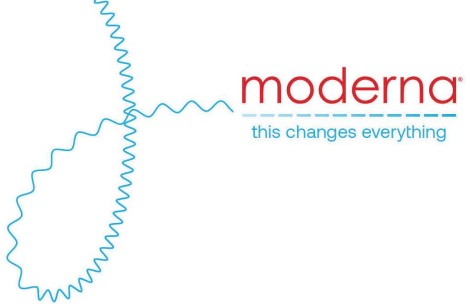
December 5th, 2022

Moderna Canada is a recently established biotechnology company and since the pandemic, have been working tirelessly to ensure that all Canadians are protected against COVID-19. In addition to this, we have made significant efforts to ensure that Canada will be ready for the next pandemic, have secure supply of respiratory vaccines for the future and contribute to the life sciences ecosystem in Canada.

The success of our COVID vaccine has allowed Moderna to explore new therapeutic areas such as oncology and rare diseases that have the potential to revolutionize therapeutics in the years to come using our proven mRNA platform. As we think about these launches in oncology and rare diseases, pricing uncertainty contemplated by the new PMPRB guidelines remains a major concern. Launching new therapeutics is a global decision and as the Canadian affiliate, we need to be able to clearly identify the environment in which we are planning to bring our products to market, including pricing considerations. We recognize that the government of Canada has acknowledged that unpredictable regulatory regimes halt future investment, and has moved to champion a number of multilateral and bilateral trade agreements that seek to ensure international border-in predictability.

Domestic pricing environment makes the launch of any future medicines more challenging, with riskier jurisdictions potentially getting delayed access. In the best case scenario, pricing uncertainty leads to global de-prioritization of launch order amongst the launch countries which will have implications to Canadian patients who deserve timely access to life saving therapies. In addition to this, PMPRB's interpretation of excessive price (median of the basket) and ignoring the level of therapeutic benefit that a new drug brings to patients in setting its price are concerning and has the potential to significantly impact launch decisions for Canada.

The implications of policy changes should be quantifiable, and all efforts should be taken to assess both the intended and unintended consequences of these new proposals. Moreover, they should be synergistic with other strategies in the life sciences sector in Canada that are aimed at making Canada an attractive destination for life sciences. If there is one thing we learned from the pandemic, it was that when the outcome, ambition and roles and responsibilities were clear, we were able to work together to achieve success. Thus, pricing reform presents an opportunity to review systems that currently exist in Canada and identify what is needed to achieve access to medicines for Canadians, foster innovation in Canada while protecting consumers from excessive pricing. We are



hopeful that true collaboration between the right parties can achieve this goal for the betterment of all Canadians.

For our part, Moderna is excited to have partnered with Canadian federal and provincial governments to bring mRNA manufacturing to Canada. It is our hope that these new and innovative products will spur greater research partnering and be acknowledged for the groundbreaking work they represent, via a globally competitive and balanced pricing regime.

Sincerely,

*Patricia Gauthier*

Patricia Gauthier  
President & General Manager, Moderna Canada